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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,825	12/15/2006	Paul Boulange	1217-0181PUS1	2356

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
02/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,825	BOULANGE ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060817*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group II, drawn to an aqueous albumin solution in the reply filed on October 28, 2009 is acknowledged. The traversal is on the ground(s) that the application fulfills the unity of invention requirement as the present invention relates to an albumin purification method that provides a novel and inventive composition. Further, the applicants state no unity of invention objection was raised during the international phase. This is not found persuasive because the composition is not considered to be an inventive composition (see office action art rejection below). In addition, this is not found persuasive because the procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office. Applicant is referred to 35 U.S.C. 372 (b) (2) that states the Director may cause the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of the treaty and Regulations.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-14 and 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 28, 2008.

3. Claims 15-18 are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date is February 27, 2004.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on August 17, 2006 is being considered by the examiner. A signed 1449 form is attached with the instant office action.

Specification

6. The disclosure is objected to because of the following informalities:

7. The specification is missing a brief description of the drawings title section.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Regarding the method of forming the aqueous albumin solution, it is the position of the examiner that such limitations in the product claim are merely product-by-process limitations. The claims recite that the aqueous albumin solution are formed via a nanofiltration method; however these claims are drawn to a product. Regardless of how the product is made the components remain the same and as such the process of making the product bears little patentable weight, unless the process produces a materially different product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

11. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/04367 in view of EP 0 570 916, and Winge (U.S. Patent 6,399,357 B1).

WO 92/04367 discloses in general a process of separation of proteins and in particular albumin by the use of dyes immobilized on column of ion-exchange resins (cation and anion exchanger). Thus, the reference discloses a method for purification of albumin, which makes use of fatty acid having specific affinity for albumin, as sodium caprylate (octanoate) to elute albumin from an ion exchange resin. The reference also alludes to a purification method for albumin, where use is made of Cibacron Blue dyes to a stationary phase and serving as an affinity resins (See e.g. abstract, page 6 and 8). On pages 9-10, the reference shows the use of salts (chloride ions and octanoate ions), buffers and fatty acids at various concentrations and pHs for eluting the protein from the column containing protein-binding compound. Also, on page 11, Figure 1 and Examples 1-3, the reference teaches the use of Cibacron Blue dye and a spacer in a column to purify human albumin.

Although, the primary reference suggests the use of an alternative method for purification of albumin, and in view of this, one of ordinary skill in the art would have understood that additional steps to obtain an albumin of sufficient purity; therefore, one of ordinary skill in the art would be motivated to look for a supplementary steps which could assure the intended product to achieve the required purity.

Filtration is routine operation to improve the purity of a protein and moreover ultrafiltration and removal of salts are used in the primary reference as final steps as well as in EP 0 570 916. Further, one ordinary skill in the art would be motivated to employ nanofiltration, because Winge discloses the purification albumin using a nanofilter (see particularly claims 14-16).

Further, the production of albumin from genetically modified yeast is a routine technique (See e.g., EP 0 570 916). The reference of EP 0 570 916 teaches a method of purifying human serum albumin by combination of steps subjected to ultrafiltration, heat treatment, acid treatment and another ultrafiltration, followed by subsequent treatments with a cation exchanger, a hydrophobic chromatography carrier and an anion exchanger, and by salting-out to thereby obtain a pure form of human serum albumin free of contaminants (See abstract). The reference also discloses a method where use is made of NaCl solution in acetate buffer, and in general demonstrates that fatty acids and acids and their salts to be useful for elution from albumin from cation exchange resins, and a method for albumin purification, where a cation exchanger step precedes an anion exchange step (See e.g. summary of the invention).

Thus, the advantages of using alternative chromatographic techniques for albumin purification is clearly disclosed. Moreover, such features of purifications are known or suggested in the art, as seen in the secondary references, and including such features into albumin purification methods of the primary reference, would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof for the intended purpose of producing pure albumin.

Therefore, in view of the above, and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known method of purifying albumin by chromatographic techniques such as ion-exchange chromatography, gel permeation and affinity chromatography, and nanofiltration to eliminate impurities from purified albumin, absent of sufficient objective factual evidence or unexpected results to the contrary.

Conclusion

12. No claims area allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 2, 2009
/ANAND U DESAI/
Primary Examiner, Art Unit 1656